Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

DATE: August 13, 2009

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

SUBJECT: Barr Laboratories Inc Recall

SUGGESTED ACTION: **Unclassified Recall; Dextroamphetamine/Amphetamine 20mg Tablets, Lot number 311756; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the product being recalled was distributed in the State of Indiana. The product identified is being recalled because the affected lot may contain some tablets exceeding weight requirements which may lead to super-potent tablets. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Barr Laboratories, Inc. issues a voluntary nationwide recall of Dextroamphetamine/Amphetamine 20mg Tablets, Lot number 311756

Contact:
Denise Bradley
215-591-8974

FOR IMMEDIATE RELEASE - August 13, 2009 - Barr Laboratories, Inc. is initiating a voluntary recall of Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate (Mixed Salts of a Single Entity Amphetamine Product) 20mg Tablets, 100 count bottles, lot number 311756. The

product identified is being recalled because the affected lot may contain some tablets exceeding weight requirements which may lead to super-potent tablets.

Potentially clinically significant adverse reactions to a supratherapeutic dose could include cardiovascular, neurologic, psychiatric and gastrointestinal reactions such as: palpitations, tachycardia, hypertension, headache, tremor, tic, dyskinesia, dizziness, blurred vision, sweating, insomnia, agitation, euphoria, mania, anxiety, restlessness, nausea, diarrhea, constipation, dry mouth, and decreased appetite.

This product can be uniquely identified as an oval peach colored tablet, debossed with b/973 on one side and 2/0 on the other side. Barr distributed the affected lot between 06/11/09 and 06/16/09. Only lot 311756 is affected by this recall.

Customers who have this lot in their possession are instructed to cease using the product and return it to their pharmacy/distributor. Wholesalers and retailers should cease distribution and examine their inventory immediately.

Consumers with questions may contact 888-742-5578 from 8:00am - 8:00pm EDT Monday-Friday.

Barr Laboratories has not received any adverse events for this product lot.

The FDA has been apprised of this action.

Any adverse reactions experienced with the use of this product should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088; by fax at 1-800-FDA-0178; by mail at MedWatch, HF-410, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at http://www.fda.gov/Safety/MedWatch/default.htm.

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